



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



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SEP 11 2003

OFFICE OF
AIR AND RADIATION

Dr. Inés R. Triay, Manager
U.S. Department of Energy
Carlsbad Field Office
P.O. Box 3090
Carlsbad, NM 88221

Dear Dr. Triay:



The U.S. Environmental Protection Agency (EPA) conducted an audit from August 5-6, 2003, of the Washington TRU Solutions (WTS) quality assurance (QA) program. The WTS QA program provides on-site surveillance of activities that are important to the containment of transuranic (TRU) waste at the Waste Isolation Pilot Plant (WIPP) site. The investigation of the activities selected for the EPA audit sample showed that WTS has properly maintained its QA program since the previous audit conducted July 9-11, 2002. The enclosed report documents the results of the EPA audit.

During the audit, the EPA: 1) verified that the recent transition from Westinghouse TRU Solutions to WTS as the prime contractor at WIPP did not diminish the implementation of the applicable National Quality Assurance (NQA) requirements; 2) verified that modifications to the WTS QA Plan do not diminish the establishment of the applicable NQA requirements; and 3) verified proper implementation of NQA-1 Element 1, "Organization."

The EPA did not identify any findings of non-conformance or concerns. No response is required from the Department of Energy's Carlsbad Field Office to this letter or the enclosed report. This letter and the report will be placed in EPA Air Docket No. A-98-49. Please contact Mike Eagle at (202) 564-9376 if you have questions regarding the report.

Sincerely,

Frank Marcinowski
Director, Radiation Protection Division

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Enclosure

cc: Ava Holland (CBFO) (w/enclosure)
Matthew Silva (EEG) (w/enclosure)
✓ Steve Zappe (NMED) (w/enclosure)

DOCKET NO:A-98-49

II-A1-50

**EPA AUDIT OF THE
WASHINGTON TRU SOLUTIONS'
QUALITY ASSURANCE PROGRAM
FOR THE WASTE ISOLATION PILOT PLANT**

**U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation and Indoor Air
Radiation Protection Division
Center for Federal Regulations
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Washington, D.C. 20460**

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TABLE OF CONTENTS

1.0	EXECUTIVE SUMMARY	1
2.0	BACKGROUND	2
2.1	Regulatory Background	2
2.2	WTS Background	2
3.0	PURPOSE AND SCOPE	3
4.0	DEFINITIONS	4
5.0	AUDITOR AND PARTICIPANTS	4
6.0	PERFORMANCE OF THE AUDIT	4
6.1	QA Plan Review	5
6.2	Evaluation of Compliance with NQA-1 Element 1, "Organization"	5
6.3	Verification of Corrective Action	5
6.4	Audit Results	5
7.0	SUMMARY OF FINDINGS AND CONCERNS	6
8.0	REFERENCES	7

Attachments

Attachment 1 Personnel Interviewed by EPA Auditor

Attachment 2 Auditor's Checklist for Element 1

1.0 EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA or Agency) conducted an audit from August 5-6, 2003, of the Washington TRU Solutions (WTS or Site) quality assurance (QA) program. The investigation of the activities selected for the EPA audit sample showed that WTS has properly maintained its QA program since the previous inspection conducted July 9-11, 2002.

WTS offices are located near Carlsbad, New Mexico at the U.S. Department of Energy (DOE) Waste Isolation Pilot Plant (WIPP), the nation's underground repository for defense-generated transuranic (TRU) radioactive waste. WTS is the DOE's performance-based management and operating (M&O) contractor at the WIPP. As such, WTS's responsibilities include the day-to-day management, operations, and maintenance of the WIPP.

The WTS QA program provides on-site surveillance of activities that are important to the containment of TRU wastes within the WIPP. In August 1997, the EPA initially determined that the WTS QA program was properly executed. During February 17-19, 1998; February 9-11, 1999; June 30, 1999; August 7-8, 2000, May 7-11, 2001; and July 9-11, 2002, EPA determined that the WTS QA program had been properly maintained since the initial approval. The purpose of this audit conducted from August 5-6, 2003 was to determine whether the WTS QA program continues to be properly maintained since last year's audit. This report documents the results of the EPA audit to verify whether or not WTS has properly maintained its QA program.

During the audit, the EPA: 1) verified that the recent transition from Westinghouse TRU Solutions to WTS as the prime contractor at WIPP did not diminish the implementation of the applicable NQA requirements; 2) verified that modifications to the WTS QA program plan do not diminish the establishment of the applicable NQA requirements; and 3) verified proper implementation of NQA-1 Element 1, "Organization."

Based on the results of these audit activities, EPA has determined that the WTS QA program continues to properly establish and implement the requirements of 40 CFR 194.22(a)(1) for items and activities important to the containment of TRU waste. 40 CFR 194.22(a)(1) includes, by reference, the requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7 to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c), and Section 17.1).

2.0 BACKGROUND

2.1 Regulatory Background

In August 1997, the U.S. Environmental Protection Agency (EPA or Agency) determined the Westinghouse TRU Solutions' compliance with requirements for quality assurance (QA) programs as set forth by 40 CFR 194.22(a), based on audits in February and June 1997 conducted under the authority of 40 CFR 194.22(e). During February 17-19, 1998; February 9-11, 1999; June 30, 1999; August 7-8, 2000; May 7-11, 2001; and July 9-11, 2002, the Agency conducted audits subsequent to the approval to confirm continued compliance. This report documents the results of the audit conducted from August 5-6, 2003, and will be made available to the public through the Agency's public dockets, as described in 40 CFR 194.67.

At 194.22(a), EPA requires the Department of Energy (DOE) to adhere to a QA program that implements the requirements of the following: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The Agency verified that DOE established these requirements in the Quality Assurance Program Document (QAPD) included in the Compliance Certification Application (CCA) for the Waste Isolation Pilot Plant (WIPP). The QAPD is the documented quality assurance program plan for the WIPP project, as a whole, to comply with the NQA requirements. The QAPD is implemented by DOE's Carlsbad Field Office (CBFO), which has the authority to audit all other organizations associated with waste disposal at the WIPP to ensure that their lower-tier quality assurance programs establish and implement the applicable requirements of the QAPD.

The EPA periodically audits Department of Energy's (DOE) Carlsbad Field Office (CBFO) and has found that CBFO's QA Organization can properly audit the generator sites' QA Programs. During an EPA audit, the EPA assumes all responsibilities associated with assessing a QA Program. During an EPA inspection, the Agency performs some oversight of CBFO's checks of a generator site's QA program. Further, EPA performs some independent assessment, or audit-type, activities during the course of inspecting a CBFO audit.

2.2 WTS Background

Washington TRU Solutions (WTS) is the DOE's performance-based management and operations (M&O) contractor at the WIPP. As such, WTS's responsibilities include the day-to-day management, operations, and maintenance of the WIPP. WTS offices are located near Carlsbad, New Mexico at the WIPP, the nation's underground repository for defense-generated transuranic radioactive waste.

The EPA requires the establishment and implementation of QA programs for all activities important to the containment of TRU waste at the WIPP. As the WIPP M&O contractor, WTS

must properly execute a QA program that controls all WIPP activities important to the containment of TRU waste.

Washington TRU Solutions is the successor organization to the Westinghouse TRU Solutions. Throughout this report, references to legacy documents developed by Westinghouse TRU Solutions that are still active in the new organization will be referenced without the use of an acronym in order to differentiate from documents developed by the current M&O contractor, WTS.

3.0 PURPOSE AND SCOPE

Section 194.22(a)(1) requires that the WIPP establish and implement the requirements of: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The purpose of this EPA audit was to confirm the continued compliance of WTS's QA Program with the above requirements.

Section 194.22(a)(2) requires that WIPP properly execute a QA Program for all items and activities that are important to the containment of TRU-waste at the WIPP. The scope of this EPA audit was WTS's QA Program's oversight of items and activities that are important to the containment of TRU waste at the WIPP. Section 194.22(a)(2) reads as follows:

- (2) Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:
 - (i) Waste characterization activities and assumptions;
 - (ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;
 - (iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;
 - (iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;
 - (v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;
 - (vi) Design of the disposal system and actions taken to ensure compliance with design specifications;
 - (vii) The collection of data and information used to support compliance application(s); and
 - (viii) Other systems, structures, components, and activities important to

the containment of waste in the disposal system.

WTS also oversees waste characterization (WC) activities at selected generator sites under the Central Characterization Program (CCP). EPA audits the QA programs controlling these additional WC activities under separate site-specific CCP audits. These CCP WC activities are excluded from the scope of this audit because the WTS QA Program does not oversee the CCP WC activities.

4.0 DEFINITIONS

Finding: A determination that a specific item or activity does not meet a requirement under an applicable element of the NQA standards. A finding requires a response.

Concern: A judgment that a finding may occur in the future, and depending on the magnitude of the issue, may or may not require a response.

Quality: The reliability of a specific item or activity that is important to the containment of TRU-waste at the WIPP. *Quality Achievement* is the responsibility of operational groups that directly produce such an item or perform such an activity. *Quality Verification* is the responsibility of QA Organizations that do not produce such items or perform such activities. A failure to achieve quality is not the responsibility of the QA organization that verifies quality achievement. Further, demonstrations that quality has been achieved are the responsibility of operational groups that are responsible for *Quality Achievement*.

5.0 AUDIT TEAM AND PARTICIPANTS

The EPA auditor was Mr. Bob Thielke of Trinity Engineering Associates, Inc., a contractor of EPA's Office of Radiation and Indoor Air, Radiation Protection Division, Center for Federal Regulations. (A list of WTS and DOE personnel who were interviewed by the EPA auditor is presented in Attachment 1 of this report.)

6.0 PERFORMANCE OF THE AUDIT

During the audit, the EPA auditor:

- verified that the recent transition from Westinghouse TRU Solutions to WTS as the WIPP M&O contractor did not diminish the establishment of the applicable NQA requirements;

- verified that recent changes to the WTS QA program plan do not diminish the establishment of the applicable NQA requirements; and
- verified proper implementation of NQA-1 Element 1, "Organization" at the WIPP site.

6.1 QA Plan Review

EPA reviewed the WTS Quality Assurance Program Description, WP-13-1, Revision 24, to identify changes since the last EPA audit. The auditor evaluated each of the changes and determined that the changes to the QA plan between Revisions 23 and 24 do not diminish and, in fact, appear to enhance the establishment of the NQA requirements as applicable to the scope of this audit.

The EPA auditor did not identify any findings or concerns related to this review.

6.2 Evaluation of Compliance With NQA-1 Element 1, "Organization"

The EPA auditor interviewed the WTS quality assurance staff to verify their continued commitment to the quality assurance program as described in the QA plan. The auditor determined that WTS management was committed to quality assurance and that the QA organization had adequate resources and independence to perform their duties.

The EPA auditor determined that the requirements of NQA-1 Element 1 were adequately assessed by CBFO and that WTS had adequately implemented their QA organization in compliance with Element 1 of NQA-1. The scope for this element only addressed the QA organization of the WTS TRU waste isolation activities. The EPA checklist for this element is provided in Attachment 2.

The EPA auditor did not identify any findings or concerns related to this review of NQA-1 Element 1.

6.3 Verification of Corrective Action

No findings were issued during the EPA audit of July 9-11, 2002, so no verification of corrective action was required for this audit.

6.4 Audit Result

The EPA audit activities provided objective evidence to support that WTS has properly maintained a QA program that implements the applicable NQA requirements of 194.22(a)(1) for the items and activities important to the containment of TRU waste in the

WIPP. Based on this audit, the EPA confirmed the continued compliance of the WTS QA program approved under 194.22(a). This report will be made available to the public through the Agency's public dockets.

7.0 SUMMARY OF FINDINGS AND CONCERNS

The Agency did not identify any findings or concerns during the audit the WTS quality assurance program. Changes made in the WTS management organization after the transition from Westinghouse TRU Solutions have enhanced the organizational authority and independence of the QA organization by providing direct reporting authority to Washington Energy and Environment, the parent organization to WTS.

8.0 REFERENCES

The CBFO and WTS documents reviewed by the EPA inspectors are as follows:

1. Westinghouse TRU Solutions. "Westinghouse TRU Solutions LLC, Quality Assurance Program Description," WP 13-1, Revision 23, 10/23/02.
2. WTS. "WTS Quality Assurance Program Description," WP 13-1, Revision 24, 08/05/03.
3. WTS. "Quality Assurance Department Assessment Program," WP 13-QA.03, Revision 4, 8/27/99.
4. WTS. "WIPP Quality Assurance Program Plan for Type "B" Packaging," WP 08-PT.03, Revision 2, 06/30/03.
5. WTS. "FY2002 and FY2003 Corrective Action Log," 08/05/03
6. WTS. "FY2002 and FY2003 NCR Log," 08/05/03.
7. WTS. "Quality Assurance Fiscal Year 2003 Internal Audit Schedule," QA-03-00351, Revision 3, 06/12/03.
8. WTS. "WIPP Quality Assurance Rolling 2-Year Independent Assessment Schedule," 08/05/03.
9. WTS. "Graded Approach To Application of QA Controls," WP 13-QA3005, Revision 8, 04/14/03.

ATTACHMENT 1

PERSONNEL INTERVIEWED BY EPA INSPECTORS

ATTACHMENT 1

PERSONNEL INTERVIEWED BY EPA INSPECTION TEAM

Name	Organization and Position
Mike Lipscomb	WTS/QA Manager, Quality Assurance
Bill Allen	WTS/QA Deputy Manager, Quality Assurance
Ed Ater	WTS/QA Manager, Oversight Programs
Jon Hoff	WTS/QA Manager, Assurance Programs
Dave Wiedenhoeft	WTS/QA QA Specialist
Dave Janos	WTS/QA QA Specialist
W. Beck Anderson	WTS/QA QA Specialist
Ava Holland	CBFO/QA Manager, Quality Assurance

ATTACHMENT 2

AUDITOR'S CHECKLISTS
FOR NQA-1 ELEMENT 1

ATTACHMENT 2 - AUDITOR'S CHECKLISTS

ELEMENT: 1

TITLE: Organization

INSPECTOR: Bob Thielke

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<u>Basic Requirements</u>			
<p>1. Are the organizational structure, functional responsibilities, levels of authority, and lines of communication documented for activities affecting quality?</p>			<p>WP 13-1, Revision 24: <i>Quality Assurance Program</i> <i>Description:</i> Section 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, and 1.1.10. Figure 1-1.</p> <p>WTS Organization Chart (08/05/03)</p> <p>The Quality Assurance organization, as documented in the 08/05/03 WTS Organization Chart and Figure 1-1 of the WTS QAPD indicates that the QA organization has direct reporting responsibility to the Chairman of WTS Members Committee, Mr. Steve Marchetti, from Washington Energy and Environment. Washington Energy and Environment provides the layer of supervision directly above the Office of the General Manager for WTS. The QA organization has an Oversight Programs and an Assessments Program that reports to the Manager of Quality Assurance, Mr. Mike Lipscomb.</p> <p>The QAPD Organization chart is well defined and clearly establishes that the QA Organization has access to the appropriate levels of management, providing organizational authority. The QAPD organization chart also accurately reflects the actual lines of reporting and communication employed on a day to day basis at WTS.</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<p>2. Do persons or organizations responsible for performing quality assurance functions have sufficient authority, access to work areas, and organizational freedom to:</p> <ul style="list-style-type: none"> 10. identify quality problems; 11. initiate, recommend, or provide solutions to quality problems through designated channels; 12. verify implementation of solutions; and 13. assure that further processing, deliver, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred? 			<p>WP 13-1, Revision 24: <i>Quality Assurance Program</i> <i>Description:</i> Section 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, and 1.1.10.</p> <p>WP 08-PT.03, Revision 2: <i>WIPP Quality Assurance Program Plan for Type "B" Packaging</i>, Section 2.</p> <p>WP 13-QA3005, Revision 8: <i>Graded Approach to Application of QA Controls</i>, Revision 8, Sections 1-3.</p> <p>The current procedures and QAPD provide an indication that the QA organization has the independence and authority to identify quality problems, verify implementation of solutions, and assure that unsatisfactory conditions are controlled until a condition adverse to quality has been resolved.</p> <p>The QAPP for Type "B" packaging was reviewed to determine if WTS QA has adequate authority to control items procured under WTS contracts as well as DOE contracts. Although WTS does not have contractual authority to control unsatisfactory conditions from DOE contracted vendors, WTS has authority to not accept items that did not meet WTS QA procurement requirements. In an interview with Mr. Ed Ater, the WTS Manager of QA Oversight, he indicated that CBFO will generally assume a WTS concern of a DOE vendor as a CBFO concern. He also indicated that all vendors have adequately responded to any concerns identified by WTS QA Specialists in regards to vendor oversight.</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<p>3. Do persons or organizations responsible for performing quality assurance functions have direct access to responsible management at a level where appropriate action can be effected?</p>			<p>WP 13-1, Revision 24: <i>Quality Assurance Program</i> <i>Description:</i> Section 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, and 1.1.10. Figure 1-1.</p> <p>WTS Organization Chart (08/05/03)</p> <p>Based on the WTS Organization Chart and the QAPD, the QA Manager appears to have direct reporting authority to the Chairman of WTS Members Committee, Mr. Steve Marchetti, who supervises the Office of the General Manager. The WTS QA Manager also has a line of communication with the WTS General Manager, Mr. Steve Warren.</p> <p>In interviews with Mr. Bill Allen and Mr. Mike Lipscomb, both individuals indicated that the elevation of authority was implemented at the direction of the WTS General Manager and fully supported by the parent organization to WTS. Mr. Allen also indicated that the WTS General Manager and the Chairman of WTS Members Committee have shown a significant interest in ensuring the authority and independence of the QA organization and have demonstrated that commitment through their support of QA activities, corrective action requests, and non conformance resolution.</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<p>4. Do persons or organizations responsible for performing quality assurance functions report to a management level that provides the required authority and organizational freedom, including sufficient independence from cost and schedule considerations?</p>			<p>WP 13-1, Revision 24: <i>Quality Assurance Program</i> <i>Description:</i> Section 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, and 1.1.10., 1.1.3, 1.1.4, and 1.1.5. Figure 1-1.</p> <p>WTS Organization Chart (08/05/03)</p> <p>The WTS Organization Chart and Figure 1-1 of the QAPD graphically demonstrate reporting responsibility to the Chairman of the WTS Members Committee. The QAPD indicates that the QA organization will have the required authority and organizational freedom. Based upon review of the WTS Organization Chart and upon interviews with WTS QA Specialists, there appears to be adequate independence from cost and schedule. WTS has provided adequate personnel resources to fulfill the obligations of the WTS QA Program. In addition, the QA Specialists interviewed indicated that they had adequate time to meet their assigned responsibilities and that in the event they needed additional support that the QA Manager was accommodating in finding additional resources or prioritizing tasks. The QA specialists also indicate that they had never been asked to take on additional duties that impacted their ability to meet their responsibilities. Based upon the results of interviews with the QA Management and several QA Specialists, it appears that the QA Organization is adequately funded and has independence from cost considerations.</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<u>Supplementary Requirements (1S-1)</u>			
<p>1. Are the organizational structure and the responsibility assignments such that:</p> <p>1a. quality is achieved and maintained by those who have been assigned responsibility for performing work, and</p> <p>1b. quality achievement is verified by persons or organizations not directly responsible for performing the work?</p>			<p>WP 13-1, Revision 24: <i>WTS Quality Assurance Program Description</i>: Sections 1.1, 1.1.4, 2.1, 2.1.1, 2.4.1.1, and 2.4</p> <p>Section 2.1 of the QAPD describes responsibilities for work processes. The QAPD clearly indicates that individuals responsible for the work have a responsibility to perform quality work and that quality achievement is verified by persons or organizations not directly responsible for performing the work.</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<p>2. Does the individual(s) or organization(s) responsible for establishing and executing a quality assurance program delegate any or all of the work to others, and if so, does the individual(s) or organization(s) retain responsibility for the quality assurance program?</p>			<p>WP 13-1, Revision 24: <i>Quality Assurance Program Description</i>: Section 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, and 1.1.10.</p> <p>WP 13-QA3005, Revision 8: <i>Graded Approach to Application of QA Controls</i>, Revision 8, Sections 1-3.</p> <p>WTS Organization Chart (08/05/03)</p> <p>The WTS Organization Chart illustrates the organizational lines of authority to delegate quality assurance activities as well as line work processes. The only activity the QA organization delegates is the assignment of a QA level for an activity. The cognizant engineer for an activity will make an assignment under a clearly defined assignment checklist. However, the WTS QA Manager has signature approval authority over the resulting assignment of a QA level.</p> <p>The WTS QA Organization retains responsibility for all aspects of the WTS QA Program.</p>
<p>3. Is responsibility for the control of further processing, delivery, installation, or operation of nonconforming items designated in writing?</p>			<p>WP 13-1, Revision 24: <i>WTS Quality Assurance Program Description</i>: Section 1.3.</p> <p>Modifications to the QAPD clarified that the WTS QA Organization has the authority to control unsatisfactory activities until a satisfactory resolution verified by the WTS QA Organization is implemented.</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<p>4. Where more than one organization is involved in the execution of quality assurance activities, is the responsibility and authority of each organization clearly established and documented?</p>			<p>WP 13-1, Revision 24: <i>WTS Quality Assurance Program Description</i>:: Section 1.1.9. Figure 1-1.</p> <p>WTS Organization Chart (08/05/03)</p> <p>All QA staff are WTS employees. Although WTS interfaces with multiple QA organizations in conjunction with the CCP waste characterization process. The scope of this audit only includes TRU waste isolation related activities, and was therefore not evaluated. The QA adequacy of individual CCP programs are typically audited under separate audit scopes and technical direction.</p> <p>Based upon the scope of this audit, WTS has a single QA organization.</p>
<p>5. Are the external interfaces between organizations, as well as the internal interfaces between organizational units, documented? Are interface responsibilities defined and documented?</p>			<p>WP 13-1, Revision 24: <i>Quality Assurance Program Description</i>: Section 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, and Figure 1-1.</p> <p>WTS Organization Chart (08/05/03)</p> <p>The interfaces between external organizations are clearly documented and defined in the QAPD.</p>